

NOTE TO FILE

Subject: Monsanto's Bt-Resistant (Bollgard™) Cotton Lines 757 and 1076

Keywords:

Cotton, Cotton Bollworm, Tobacco Budworm, Pink Bollworm, *Bacillus thuringiensis* subsp. *kurstaki*, APH(3')II, NPTII, *cryIA(c)*, Bt-toxin, Insect Resistance, Pesticide.

Background

In a submission dated February 27, 1995, Monsanto provided summary information to support their safety assessment of cotton lines 757 and 1076. Based on this information, these cotton lines were developed using similar procedures and with the same intended technical effect as their cotton line 531. Because of the similarities between this submission and Monsanto's previous submission on their cotton line 531 dated November 21, 1994, this note to the file will only address topics that differ among these three cotton lines.

According to Monsanto, the inserted DNA is capable of expressing two proteins: 1) Bt-toxin; and 2) aminoglycoside 3'-phosphotransferase II (APH(3')II). Because the *aad* gene (3'(9)-O-aminoglycoside adenytransferase) is under the control of a bacterial promoter, expression from this gene in cotton plants would not be anticipated. Monsanto reported that they confirmed that this gene is not expressed in their cotton lines 757 and 1076.

Because the safe use of Bt-toxins as pesticides is regulated by the Environmental Protection Agency (EPA) under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), and because EPA has exempted from the requirement of a tolerance residues of APH(3')II and the genetic material necessary for its production when used as a plant pesticide inert ingredient (59 FR 49351; September 28, 1994), this note to the file does not address the safe use of Bt-toxin as a pesticide or the use of APH(3')II¹ as a pesticide inert ingredient. Therefore, we limit our comments to the nutritional and toxicant properties of lines 757 and 1076.

¹FDA has approved the food additive use of the APH(3')II enzyme in the development of genetically modified cotton, oilseed rape, and tomatoes (59 FR 26700; May 23 1994)

Conclusions

Monsanto has concluded that their: "Bollgard Cotton Lines 757 and 1076 are not materially different from cotton varieties now being sold in any meaningful way except for the ability to resist feeding by lepidopteran insect pests." Moreover, Monsanto has concluded that: "Sales and consumption of cotton seed derived from this variety would be fully consistent with the Agency's Food Policy, the Federal Food, Drug, and Cosmetic Act, and current practices for the development and introduction of new cotton varieties."

At this time, based on Monsanto's description of its data and analyses, the Agency considers Monsanto's consultation on their cotton lines 757 and 1076 to be complete.

Dennis M. Keefe, Ph.D.